UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,809	02/05/2004	Joel E. Bernstein	41957-102748	5946

23644 7590 01/28/2009

BARNES & THORNBURG LLP
P.O. BOX 2786
CHICAGO, IL 60690-2786

EXAMINER
CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
01/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/772,809	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/2008 has been entered.

Response to Arguments

Applicants present arguments over the 35 USC 112 rejection. In particular, Applicants argue that there was possession of claims 11, 13 and 16 and that there is no new matter in the claims. Applicants state that a unit dose can be smaller than a daily dose. Applicants assert that the unit dose range of claim 13 falls within the daily dose ranges taught. Applicants feel that they have provided extensive evidence that there was possession of the invention at the time of filing.

While the Examiner appreciates Applicants arguments and fully understands the difference between daily dose and unit dose, the above arguments are still not found to be persuasive for claims 13 and 16. However, upon further consideration the rejection is being dropped for claim 11 as there is support in the specification for doxepin in daily doses of 2.5 – 10 mg. The claimed subject matter of claims 13 and 16 was not described in the specification in such a way as to lead one of ordinary skill in the art to

envision the particular claimed ranges in question. In particular, the specification teaches that the standard dose of non-narcotic analgesic is 0.5 gm – 2.6 gm daily and gives specific ranges within that for acetaminophen, aspirin and ibuprofen. It is completely understood that the unit dose can be smaller than the daily dose and Applicants give a range in claim 13 of 25 mg to about 1 gm. Though Applicants assert that this range is taught within the ranges listed in the specification, there is nothing in the specification that would lead one to envision this particular range limitation. Furthermore, the specification only eludes to unit doses in the specification in Example 2 in which both compositions were administered twice a day. There is nothing in the examples to lead one to envision a claimed unit dose range of 25 mg to about 1 gm. The claimed range in claim 13 is not inherently disclosed in the range of daily doses taught in the specification. Claim 17 was previously not included in the rejection; however, upon further consideration claim 17 should be included in the rejection because there is no teaching in the specification that would envision a range of 50 mg to about 2.6 gm daily because the specification teaches a daily dose range of 0.5 - 2.6 gm daily (corresponding to 500 mg – 2600 mg). There is no support for any amounts under 500 mg. Regarding claim 16, it is noted that the specification teaches that the tricyclic antidepressants are given at 2.5 mg - 25 mg daily, more preferably 5 mg - 20 mg daily and more preferably 10 mg - 15 mg daily. However claim 16 recites a unit dose of the tricyclic antidepressant at 10 mg or less. This is not correct because there is no lower limit and causes the claim to literally read on embodiments below that taught in the specification (including zero).

Further, it is noted that the specification only teaches the daily dosage amount and gives no indication as to how many times per day the compositions need to be administered in order to determine unit dosage amounts. The examples only teach administration at once or twice per day and even if you apply that to the daily ranges taught, the claimed ranges of the unit doses do not fall within that range. Accordingly, the rejection is maintained and appropriate correction is required.

Applicants further argue over the 35 USC 102(b) rejection over Caruso that it is a paper patent application and there are no results. Applicants assert that Caruso would not lead one of skill in the art to believe that non-narcotic analgesics and tricyclic antidepressants are sufficient to alleviate chronic pain and that NMDA receptor blockers are essential to Caruso. Applicants argue that the "consisting essentially of" language in claim 9 of the present application excludes the NMDA receptor blockers as taught by Caruso because they are a necessary element.

In response to the above arguments, it is noted by the Examiner that the case law meaning of "consisting essentially of" means that it includes only materials specified in the claim "and those that do no materially affect the basic and novel characteristics of the claimed invention" (see MPEP 2111.03). Applicants have not provided evidence that the composition of the present claims will provide the same efficacy or enhanced efficacy with the tricyclic antidepressant and the non-narcotic analgesic alone compared to the composition of Caruso. Absent a clear showing of unexpected results, the composition claims are considered anticipated by the compositions taught by Caruso. Therefore, the rejection is deemed proper and is maintained.

Applicants argue over the 35 USC 102(b) rejection over Kakuyama that because Kakuyama is a literature review on antidepressants and no actual tests were run, no doses recommended, and no combination of tricyclic antidepressants and non-narcotic analgesic were mentioned, that the reference is not an anticipating publication. Applicants point to the subject of the rejection and assert that Kakuyama et al. does not suggest a combination of drugs and refers only to a second hand report from Goldenberg in which the combination was just as effective as the antidepressant alone.

In response to the above arguments, the Examiner would like to point out to the Applicant that the present claims are drawn to a composition consisting essentially of a low dose of tricyclic antidepressant and a standard dose of a non-narcotic analgesic. It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9, namely that the composition is for treatment of chronic pain is not afforded patentable weight. Therefore, as the claim is being examined as it reads on a composition and as the prior art teaches the same composition then the art reads on the claim. Furthermore, Kakuyama teaches dosage ranges that fall within that claimed. Therefore, the prior art anticipates this claim limitation and the rejection is maintained.

Applicants have presented arguments over the 35 USC 103 rejection and set forth the same arguments over Kakuyama as applied above; therefore, those arguments have been addressed accordingly.

Applicants have further presented arguments for the 35 USC 103 rejection over Crawford in view of Lombardino. Applicants point to the argument using *in re Aller* discussing optimization of dosage ranges and that doses of one class of drugs cannot be extrapolated to another (according to the *in re Aller* decision).

In the instant case, Crawford et al. teaches compositions comprising piroxicam (NSAID) and doxepin (antidepressant). Crawford et al. teaches using lower amounts of piroxicam than claimed; however, Lombardino supports the argument of optimizing ingredients because Lombardino teaches higher amounts of piroxicam that produce anti-inflammatory effects. Because the NSAID piroxicam is being used in both references for the same purpose, it would be obvious to optimize the amount to increase the effectiveness of the compound. Generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that the particular claimed concentration is critical. Therefore, it is well within the skill in the art to optimize the amount of piroxicam to provide maximal effects.

Accordingly, the following rejections are being maintained and are given below for Applicant's convenience.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification as originally filed does not provide support for a composition having a non-narcotic analgesic in "unit doses of from about 25 mg to about 1 mg," as recited in claim 13, a composition having a tricyclic antidepressant "in unit dosages containing 10 mg or less," as in claim 16 or the analgesic administered in a dosage of from about 50 mg to about 2.6 gm daily as in claim 17. Instead, the specification teaches that the non-narcotic analgesic may be provided in amounts of from 0.5 grams to 2.6 grams daily (see paragraph 00010, in particular), but does not teach a composition having the smaller range of from 25 mg to 1 gm of non-narcotic analgesic (unit dose), as recited in claim 13. The specification also teaches that suitable daily dosages of the tricyclic antidepressant may be in the range of about 2.5 mg to about 25 mg daily (see paragraph 00011, in particular), but does not teach specifically providing the tricyclic in range of 10 mg or less, as recited in claims 11 and 16. Accordingly, as claims 13, 16 and 17 are not fully supported by the

specification as originally filed, these claims are deemed to add impermissible new matter, and are rejected under 35 U.S.C. 112, first paragraph. Appropriate correction is required.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50044 to Frank S. Caruso, published November 12, 1998.

Caruso teaches treating neuropathic pain with a composition having an antidepressant (see abstract, in particular). Caruso teaches that the antidepressant can be a tricyclic antidepressant such as imipramine hydrochloride, doxepin hydrochloride, among others (see page 4, lines 1-19, in particular). Caruso teaches that an oral method of administration can be employed, and the composition may be provided as

tablets or hard capsules, which are pharmaceutically acceptable vehicles (see page 6, lines 5-12, in particular). Caruso furthermore teaches that the composition can have a non-narcotic analgesic such as acetaminophen or naproxen (see page 7, lines 10-24, in particular). Caruso also teaches that the composition can be formulated to provide a desired dosage level of the components per day, and teaches formulating with pharmaceutically acceptable ingredients and excipients (carriers) (see page 5, lines 20-25 and page 6, lines 10-25, in particular). Caruso teaches that the dosage forms be coadministered in a single dosage form (page 6, lines 5-12).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 9-15, Caruso teaches exemplary tablet dosage forms having antidepressant drugs and an additional active component that is a non-narcotic analgesic (see page 10, lines 5-37, in particular). Regarding claims 11-12 and 14-15, Caruso teaches that the tablet form can comprise compositions with 25 mg of imipramine hydrochloride and 325 mg of aspirin or acetaminophen (see examples 36 and 37, in particular). Thus, Caruso teaches the composition having the claimed tricyclic antidepressant compounds and non-narcotic analgesics, and also teaches the claimed pharmaceutically acceptable vehicle.

Regarding claims 9-10, Caruso's teaching of 25 mg of imipramine hydrochloride is considered to meet the limitation of being from "about" 2.5 mg to "about" 25 mg daily as recited in claim 10.

Regarding claims 9, 13 and 17, Caruso's teaching of 325 mg of acetaminophen is considered to meet the limitation of being a "standard dose" of non-narcotic analgesic compound as claimed, because it falls within the range of "about 0.5 grams to about 2.6 grams," in accordance with the Applicants' guidance of a suitable "standard dose," which is set forth in the second full paragraph on page 3 of Applicants' specification. In particular, 325 mg of acetaminophen is considered to be within the range of "about" 0.5 grams to "about" 2.6 grams, as set forth by Applicants, as well as the dose of from about 25 mg to about 1 gm as in claim 13, and about 50 mg to about 2.6 grams, as recited in claim 17.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9,

namely that the composition is for treatment of chronic pain is not afforded patentable weight.

Accordingly, the tablet dosage forms taught by Caruso anticipate the compositions of claims 9-15 and 17.

Claims 9-11, 13-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128.

Kakuyama et al. teaches treatment of chronic pain with antidepressants, noting that the efficacy of treatment of chronic pain with antidepressants has been assessed in many randomized controlled studies, and that tricyclic antidepressants are the first line treatment for chronic pain such as postherpetic neuralgia and painful diabetic neuropathy, and are also effective for migraine and chronic tension-type headache (see abstract, in particular).

Kakuyama et al. teaches that patients suffering from fibromyalgia achieved significant improvement in their condition after receiving naproxen (an NSAID) in an amount of 1000 mg/day and amitriptyline in an amount of 25 mg each night, for a duration of six weeks (see page 125, right had column fourth full paragraph, in particular). Thus, Kakuyama et al. teaches the desirability of providing a non-narcotic

analgesic in an amount that meets the limitation of being a "standard dose," as defined by Applicants on page 3 of the specification, as well as recited in instant claim 17, and administering the combination separately one right after the other (as recited in claim 9).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

Regarding claims 11 and 14, Kakuyama et al. teaches providing amitriptyline and naproxen (and NSAID), and thus teaches providing the tricyclic antidepressant and NSAID, as recited in the claims.

Regarding claims 13 and 16, it is noted that Kakuyama et al. teaches a daily dosage of amitriptyline and naproxen that is efficacious in the treatment of fibromyalgia, as discussed above.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9, namely that the composition is for treatment of chronic pain is not afforded patentable weight.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "The Role of Antidepressants in the Treatment of Chronic Pain" by Kakuyama et al, 2000, Pain Reviews, Vol. 7, pages 119-128, as applied to claims 9-11, 13-14 and 16-17 above, and further in view of WO 98/50044 to Caruso et al, published November 12, 1998.

Kakuyama et al. is applied as discussed above, and renders obvious a composition comprising amitriptyline and a "standard dose" of naproxen for the treatment of fibromyalgia.

Kakuyama et al. does not specifically teach providing the amitriptyline in the form of one of the acid addition salts as recited in claim 12. Kakuyama et al. also does not specifically teach the pharmaceutically acceptable vehicles such as tablets, capsules, caplets, etc, as recited in claim 15.

Caruso et al. teaches that it is known to provide the anti-depressant amitriptyline as a pain-relieving agent in the hydrochloride salt form (see page 4, in particular). Caruso et al. also teaches that it is known to deliver drugs such as antidepressants in pharmaceutically acceptable forms such as tablets or hard capsules (see page 6, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the hydrochloride salt form of the amitriptyline as taught by Caruso et al, as well as to provide the amitriptyline and naproxen combination in the form of a tablet or hard capsule, in the composition and method of Kakuyama et al, because Kakuyama et al. teaches that the combination can be suitably administered for the treatment of fibromyalgia, whereas Caruso et al. teaches that the hydrochloride salt form and tablet of hard capsules are suitable forms for the administration of the pharmaceutical drugs. Accordingly, one of ordinary skill in the art would have been motivated to provide the hydrochloride salt form and tablet or capsule dosage form with the expectation of achieving a composition suitable for

pharmaceutical administration for the treatment of fibromyalgia. Accordingly, claims 12 and 15 are obvious over the teachings of Kakuyama et al. in view of Caruso et al.

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,579,846 to Crawford et al, issued April 1, 1986, in view of U.S. Patent No. 4,434,164 to Joseph G. Lombardino, issued February 28, 1984.

Crawford et al. teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant) (see abstract and column 3, lines 45-58, in particular). Crawford et al. teaches that the piroxicam can be provide in a range of 0.1 to 1 mg/kg/day, whereas the second ingredient, such as doxepin, can be provided separately in an amount that is generally lower than the dosages typically specified in the prior art (see column 3, lines 45-55, in particular). Crawford et al. also teaches that in a combined formulation, the proportion of each drug is the ratio of the total daily dosage of each drug when dosed alone (see column 3, lines 55-68, in particular). That is, Crawford et al. teaches that the combined formulation could comprise the (i) 0.1 mg/kg/day dose of piroxicam with (ii) the lower dose of doxepin that is taught by Crawford et al. as being provided if the drugs are administered alone (i.e. not in combination, separately). Crawford et al. also exemplifies a treatment composition comprising 20 mg of piroxicam and 20 mg doxepin

with lactose and hydroxypropyl methylcellulose (carriers), and teaches that a dosage of the piroxicam can be from 5-50 mg/day (see Example 9 and column 4, lines 1-10, in particular).

It is respectfully noted that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the intended use recited in claim 9, namely that the composition is for treatment of chronic pain is not afforded patentable weight.

Crawford et al. does not specifically teach that the compositions as exemplified comprise a "standard dose" of a non-narcotic analgesic and a low dose of a tricyclic

antidepressant, as recited in claim 9.

Lombardino teaches novel salts of piroxicam that provide anti-inflammatory activity (see column 1 line 1 through column 2 line 60, in particular). Lombardino teaches that a suitable dose of the piroxicam salt can be from 5 mg up to 1000 mg per day (see column 3, liens 18-25, in particular).

Accordingly, Crawford et al's dosage of 5 to 50 mg/day (see column 4, lines 1-10, in particular), falls within the dosage range as taught by Lombardino et al. to be useful for anti-inflammatory action, and thus is considered to be a "standard dose" of piroxicam. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the "standard" normal dose of piroxicam as taught by Crawford et al. and Lombardino, with a lower dose of doxepin, as taught by Crawford et al, with the expectation of providing a suitable anti-inflammatory composition for the treatment of gastric irritation.

Regarding claims 13 and 17, Crawford et al's teaching of 5 to 50 mg/day of piroxicam meets and/or overlaps with the limitation of being from "about 25 mg to about 1 gm," as in claim 13, and "about 50 mg to about 2.6 gm," as in claim 17. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of piroxicam provided in the composition, according to the guidance provided by Crawford et al, to provide a

composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

Regarding claims 10 and 16, Crawford et al. teaches that the dosage of doxepin can be from 4 to 200 mg/day (see column 4, lines 5-10, in particular), and exemplifies a composition with 20 mg, and thus meets the limitation of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of doxepin provided in the composition, according to the guidance provided by Crawford et al, to provide a composition having desired anti-inflammatory properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

Regarding claim 11, Crawford et al. teaches providing doxepin, as recited in the claim. Regarding claim 12, Crawford et al. teaches that doxepin is marketed in the form of its hydrochloride salt (see column 3, lines 15-20, in particular), and thus it would be obvious to one of ordinary skill in the art to provide doxepin hydrochloride because Crawford et al. teaches that this is a doxepin form that is available on the market. Regarding claim 14, Crawford et al. teaches providing piroxicam, which is a non-

steroidal anti-inflammatory. Regarding claim 15, Crawford et al. teaches that the composition can be provided as a tablet or capsule (see column 4, lines 15-20, in particular).

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617